

REMARKS

The undersigned would like to thank the Examiner and his supervisor, Examiner Gibson, for their courtesy in conducting the telephonic interview on October 24, 2006, despite the fact that the application was on final rejection status at the time.

With entry of this amendment claims 1-4, 6-14, 16, 18-19, 25-26, as well as new claims 37-42, remain pending in the application. Of these, claims 4, 9, 14, 16, 26 and (new claim) 40 are withdrawn from consideration pursuant to a previous election, but are to be reinstated and allowed upon allowance of a generic (or an intervening) claim from which the respective withdrawn claim depends. Also, Applicant would like to bring to the attention of the Examiner that co-pending U.S. Patent Application S.N. 10/669,543 (US Pub 20050065545) claims subject matter that is substantially similar to that of canceled claims 27-36 of the present application.

Withdrawal of the previous claim rejections and allowance of all remaining pending claims is respectfully requested in view of the foregoing amendments and the following remarks.

In particular, claims 1-3, 6-8, 10-13, 18-19 and 25 stand rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Ken et al. (U.S. Patent No. 5,853,418 "Ken") in view of Bose et al. (U.S. Patent No. 6,605,111 B2; "Bose").

Regarding Ken, Applicant acknowledges that Ken states that a stretch-resisting member provided for a vaso-occlusive coil device may "optionally contain modest amounts of iron." (Ken, col. 5, lines 1-2). However, there is no mention or suggestion in Ken that such "modest amounts of iron" in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member if exposed to an external energy source (e.g., MR) when the coil is implanted at a treatment site. Nor is there any mention in Ken if the "optional" modest amounts of iron would be embedded in the filament versus applied as a coating, or

otherwise. And, in particular, there is no mention in Ken that the coil itself contains, (or may optionally contain), any amount of iron, despite a very detailed description of what materials the coils are made from at lines 47-60 of column 4 of Ken.

More importantly, even if Bose may be properly combined with Ken, and Applicant does not concede that they may be so-combined, such combination does not result in the presently claimed invention.

Bose teaches that one may locate a biodegradable polymer at an internal body site by first introducing the monomer components of the polymer to the site, and then initiating the polymerization process in-situ. Bose points out that it may be necessary or desirable to employ an in-situ initiator (catalyst) for the polymerization process, and that one such initiator is “heat energy” (Col. 17, line 56). Bose also teaches that a “bioactive ingredient” may be included with the monomer components that become part of the completed polymer in-situ.

However, Bose does not teach or suggest that the bioactive agent is released from the polymer device into the treatment site (claims 1 and 18) or otherwise activated (claim 37) by application of an external energy source to heat the device after the device has been implanted at the treatment site.

Nor is there any teaching or suggestion in Bose (or otherwise set forth by the Examiner) that the device of Ken may be modified as recited in claim 42, whereby, in addition to a first material that may be heated by an external energy source while the device is implanted at a treatment site, the device is further provided with a second material having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the device if the first material is heated by the external energy source, and wherein the second material is embedded in one or more portions of the device, such that, if the device is implanted at the treatment site when heated by the

external energy source, and thereafter allowed to cool at the treatment site, the one or more portions are at least partially melted and fused together to thereby stabilize the vaso-occlusive device in a deployed configuration.

Instead, Bose very clearly teaches that the “bioactive ingredient” is released by the eventual biodegradation of the polymer device. See Col. 25, line 43-45 (“As the biodegradable polymer degrades, it releases the bioactive ingredient at the site of the device.”).

The crux of the rejection appears based on the proposition that “polymerization” means the same thing as “melted.” See, e.g., the last full paragraph on page 5 of the August 18 Office Action, which states, in pertinent part, “the examiner has provided the passage line in Bose et al. that clearly discloses that although the polymer is biodegradable it is also polymerized (*i.e., melted*) by heat energy upon which it cools, releases the bioactive agent and begins to biodegrade.” (Emphasis added). This is, however, factually incorrect and not consistent with the disclosure of Bose.

The following definitions of “polymerization,” as well as the attributed sources, are provided from www.dictionary.com:

1. The act or process of forming a polymer or polymeric compound.
2. The combination of many like or unlike molecules to form a more complex product of higher molecular weight, with elimination of water, alcohol, or the like (**condensation polymerization**), or without such elimination (**addition polymerization**).
3. The conversion of one compound into another by such a process.

Dictionary.com Unabridged (v 1.0.1)

Based on the Random House Unabridged Dictionary, © Random House, Inc. 2006.

1. The bonding of two or more monomers to form a polymer.
2. A chemical process that effects this bonding.

American Heritage® Dictionary of the English Language. Fourth Edition
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1. The bonding of two or more monomers to form a polymer.
2. A chemical process that effects this bonding.

The American Heritage® Stedman's Medical Dictionary

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1 : a chemical reaction in which two or more small molecules combine to form larger molecules that contain repeating structural units of the original molecules --- compare ASSOCIATION 4
2 : reduplication of parts in an organism

Merriam-Webster's Medical Dictionary, © 2002 Merriam-Webster, Inc.

n : a chemical process that combines several monomers to form a polymer or polymeric compound
[syn: polymerisation]

WordNet ® 2.0, © 2003 Princeton University

By way of another reference, the website www.wikipedia.com, believed to be frequently used by PTO examiners as a very credible reference to the meaning and context of claim terms, provides the following explanation for “polymerization:”

Polymerization is a process of reacting monomer molecules together in a chemical reaction to form three-dimensional networks of polymer chains (citing Introduction to Polymers 1987 R.J. Young Chapman & Hall ISBN 0-412-22170-5).

The respective dictionary definitions and Wikipedia explanation make no reference to polymerization being the same as or involving an act of “melting.” Indeed, reference to “heat energy” is made in Bose *only* in the context of heat energy being one of many possible initiators that may be used to facilitate an in-situ polymerization process. (See col. 9, lines 23-26). No further explanation is provided as to how such heat energy would be applied or what impact it would have beyond initiating the polymerization process. Certainly no reference or suggestion is made in Bose

that heat energy used as an initiator of the polymerization process may be applied from an external energy source to thereby heat the device and thereby release or activate a bioactive ingredient from such heating of the device. The act of polymerization of the device in Bose is clearly different and separate from its eventual biodegradation and release of the bio-ingredient.

For at least these reasons, independent claims 1 and 18 (as amended), as well as new independent claims 37 and 42 are believed patentable over the combination of Ken and Bose.

For at least the same reasons, dependent claims 2-3, 6-8, 10-13, 16, 19, 25, 38-39 and 41 are also believed patentable over the combination of Ken and Bose. Additionally, Applicant notes:

Regarding dependent claims 2 and 12, there is no teaching or suggestion in Bose (or otherwise set forth by the Examiner) that the device of Ken may be modified, whereby, in addition to a first material that may be heated by an external energy source while the device is implanted at a treatment site, the device is further provided with a second material having a melting or glass transition temperature greater than body temperature, but less than a temperature reached by the device if the first material is heated by the external energy source.

Regarding dependent claims 3 and 13, there is no teaching or suggestion in Bose (or otherwise set forth by the Examiner) that the second material may be embedded in one or more portions of the device, such that, if the device is implanted at the treatment site when heated by the external energy source, and thereafter allowed to cool at the treatment site, the one or more portions are at least partially melted and fused together to thereby stabilize the vaso-occlusive device in a deployed configuration.

Regarding dependent claim 6 (which depends from claim 2), there is no teaching or suggestion in Bose (or otherwise set forth by the Examiner) that the bioactive agent may be released by (at least partially) melting the second material.

Regarding dependent claims 7 and 38, there is no teaching in Ken or Bose of an external energy source for heating the device in-situ, or that such external energy source may be magnetic resonance.

Regarding dependent claims 8, 25 and 39, as pointed out above, there is no mention in Ken of how the “optional” modest amount of iron is provided in the filament, and no mention at all that iron or any other ferrous material is embedded in the occlusive coil device itself.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that all pending claims are allowable over the cited references. Accordingly, a notice of allowance is earnestly solicited. If the Examiner feels that a further telephone interview could expedite resolution of any remaining issues, he is welcome to call the undersigned at the below-listed number.

Respectfully submitted,

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